

## **Michigan Department of Community Health Bureau of Laboratories**

February 1, 2006

RE: FDA Recall Ortho-Clinical Diagnostics VITROS® Immunodiagnostic HBsAg Confirmatory Kit

### **FDA Class 1 Recall**

Ortho-Clinical diagnostics and FDA notified healthcare professionals and clinical laboratory staff of a class 1 recall of the Ortho-Clinical Diagnostics VITROS® HBsAg Confirmatory Kit. This kit is used to confirm the presence of Hepatitis B surface antigen in human blood and plasma that has initially been found to be reactive using the VITROS® Immunodiagnostic Products HBsAg Reagent Pack. An unknown component in the diluting solution used to test blood and serum samples may produce 'Not Confirmed' results for samples found to be positive with the initial test, which can cause some results to be classified as false negatives. False negative results may prevent some patients infected with or carrying the hepatitis B virus from receiving necessary treatment. This is especially true for pregnant women whose tests show false negative results. Infants born to women falsely classified as hepatitis B virus negative, will be presumed negative and not treated with hepatitis B immunoglobulin (HBIG) and hepatitis B vaccine. Such infants have a 90% chance of progressing to chronic hepatitis B infection. Perinatally acquired hepatitis B infection may be fatal.

Read the complete FDA recall notice at <http://www.fda.gov/cdrh/recalls/recall-121505.html>.

### **Save the Date**

The 2006 Michigan Rabies Conference is being held Monday, April 24 at the Kellogg Center, Michigan State University, East Lansing, Michigan. Registration materials are available at [http://michigan.gov/documents/MRC\\_SaveDate\\_145377\\_7.pdf](http://michigan.gov/documents/MRC_SaveDate_145377_7.pdf).

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